UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/487,032	06/07/1995	DOUGLAS SMITH	GTN-001	7279

7590 05/03/2002

Lahive & Cockfield LLP
28 State Street
Boston, MA 02109

EXAMINER
PORTNER, VIRGINIA ALLEN

ART UNIT	PAPER NUMBER
1645	42

DATE MAILED: 05/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/487,032	Applicant(s) Smith
	Examiner Portner	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 4, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *123, 132, 133, 149, 202, 203, 212, and 220-224* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *123, 132, 133, 149, 202, 203, 212, and 220-224* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☒ Other: *sequence letter*

DETAILED ACTION

Claims 123, 132-133, 149, 220-224 have been amended.

Claims 113-120, 124-131, 134-135, 150, 196-201, 204-211, 213-219 have been canceled.

Claims 123, 132-133, 149,202-203,212 and 220-224 are pending and under consideration.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Re-opening of Prosecution

The finality of the rejection of the last Office action is herein withdrawn.

Telephone Interview Summary

On March 28, 2002, a telephone interview was conducted between Ms. Amy. E. Mandragouras, Registration Number 36,207, Attorney for Applicant and Examiner Portner. The nature of the interview was to discuss the claim Amendments submitted After Final, dated March 4, 2002.

Prior to discussion of any claim amendments submitted After Final, the examiner pointed out a discrepancy between the originally filed Figure "HPP426" which provides original descriptive support for SEQ ID No 746 and the Sequences submitted in the Computer Readable Form (CRF), date of entry into STIC/USPTO data base being March 25, 1997.

Original Figure "HPP426" shows an amino acid sequence of 148 amino acids which starts with "Met" and ends with "Cys" (see attachment page, filed 1995).

The sequence listing page for SEQ ID NO 746, the sequence searched using the CRF submitted by Applicant and examined in the Office Actions, shows an amino acid sequence of 170 amino acids (1997), rather that an amino acid sequence of 148 as originally submitted (1995).

Additional changes in the amino acid sequence are evident in the sequence listing page (1997) that are not supported by original Figure HPP426 (1995). "Xaa" designators have been inserted in positions 3-4 and 146 and the specific amino acids originally submitted deleted. The last amino acid "Cys" of position 148 of HPP426 is not present in the Sequence listing page, but has been substituted with "Leu".

Based upon the discrepancies between the originally filed figure HPP426, the SEQUENCE LISTING PAGES, and the CRF submitted, the examiner stated that prosecution would be re-opened and a New Matter Rejection would be made of record. The Amendment After Final would be entered upon Re-opening of prosecution and a Non-Final Office Action made of record. Prosecution is being re-opened in light of a lack of original descriptive support for the sequence(s) shown in the SEQUENCE LISTING PAGES and CRF.

Response to Amendment

2. The Declaration of Dr. Peter C. Doig under 37 CFR 1.132 filed March 4, 2002 is insufficient to overcome the rejection of claims 123, 132-133, 149, 220-224 based upon 35 U.S.C. 101, and 35 U.S.C. 112, first paragraph as set forth in the last Office action because:

Dr. Doig discusses a polypeptide that does not evidence original descriptive support in the instant Application. Dr. Doig refers to amino acids 24 through 155 of SEQ ID No 764, but SEQ ID NO 764 (original) only contains 148 amino acids. The evidence and arguments provided in the Declaration are not commensurate in scope with the claimed invention which evidences original descriptive support in the Instant Application. No specific epitopes are disclosed. The specific function of SEQ ID NO 764 was not described to be HopE in the instant Application. The polypeptide discussed by Dr. Doig is a different molecule from that originally disclosed in the instant Application.

Defective Appeal Brief

The brief does not contain a statement of the status of all the claims, pending or canceled, and identify the claims appealed as required by 37 CFR 1.192(c)(3). The claims recited in the Appeal Brief and Arguments directed to the rejections made of record are directed to a molecule of 170 amino acids in length that does not evidence original descriptive support in the instant Application. Based upon this fact, the Appeal Brief submitted March 12, 2002, is defective.

Request for An Oral Hearing

In light of prosecution having been re-opened, the instant Application is no longer on Appeal. Applicant's request for an Oral Hearing by the Board of Appeals is deferred and should be resubmitted at such time if and when the instant Application is on Appeal again. The status of the instantly claimed invention is now in "Non-Final Status", in light of the examiner re-opening prosecution, in order to make of record new grounds of rejection, at least under 35 U.S.C. 112, first paragraph, New Matter.

Sequence Letter

3. Not withstanding Applicant's Declaration pursuant 37 CFR 1.182, that the sequences submitted in electronic form (CRF) and paper copy (SEQUENCE LISTING PAGES) do not evidence New Matter, the description and figures originally submitted with the instant Specification, do not provide original descriptive support for the sequences present in the CRF and sequence pages submitted in 1997. The sequences submitted in 1997 are not identical to those submitted in June 1995. The following sequence letter requirement is being made in light of fact that the original sequences and those submitted in 1997 are not identical. Resubmission of a CRF and sequence listing that are identical to those originally filed is required.

4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However,

this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

5. APPLICANT IS GIVEN the time period set for THIS LETTER WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.R.F. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

6. Please see attached copy of original figure HPP426 and Sequence Listing page for SEQ ID NO 764 that show clear differences in sequence structure.

Specification

7. The disclosure is objected to because of the following informalities: The figures and the sequence pages do not correspond one to the other. The lack of agreement between the sequence listing and the figures introduces confusion into the disclosure. Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 123, 132-133, 149, 202-203, 212 and 220-224 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. All of the claims recite SEQ ID No 764, which is defined by the computer readable form (CRF) and Sequence listing pages (now a part of the instant Specification) that show an amino acid sequence of 170 amino acids. Original figure HPP426 which was given the designator SEQ ID No 764 as well, only shows an amino acid sequence of 148 amino acids. All pending claims recite SEQ ID NO 764 which contains at least 32 additional amino acids that do not evidence original descriptive support in the instant specification. Other changes were made to the CRF and Sequence listing pages through introduction of Xaa amino acids at positions 3-4 and 146 and the original amino acids deleted. The last amino acid "Cys" of position 148 of HPP426 is not present in the Sequence listing page or the CRF submitted in 1997, but shows "Leu" at position 148.

11. Claim 123, 202-203 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 123 recites the phrase "which is a recombinant polypeptide". What is the nucleic acid sequence for the claimed polypeptide that has been produced recombinantly in light of the fact that the claimed polypeptide need only comprise 10 amino acids of SEQ ID No 764, but is not limited in size to 10 amino acids?

Claim 132 recites the phrase "a polypeptide of any one of claims 202-203 and an additional amino acid sequence." In light of the fact that the amino acid sequence of the claimed polypeptide of claims 202 and 203 is not limited to an amino acid sequence that encodes an epitope or antigenic determinant, what is the fusion polypeptide now claimed? What amino acids have been fused with the polypeptide amino acids sequence of either claim 202 or 203? What the fusion protein is, is not clear in light of the polypeptide of claims 202-203 not being specifically defined by any over all structure and function and the additional amino acid sequence is not provided either.

Claim 202 recites the phrase "at least one epitope recognized by a T-cell receptor specific for the polypeptide set forth in SEQ ID NO 764." What is the epitope that is recognized by a T cell receptor? What is the polypeptide sequence that comprises the T-cell receptor epitope? How large is the polypeptide? What is the over all structure, sequence and function of the claimed

polypeptide, especially in light of the evidence made of record showing sequence homology between Hemophilus, Helicobacter and Trichoderma longibrachiatum ?

Claim 203 recites the phrase "at least antigenic determinant of the polypeptide set forth in SEQ ID NO 764." What is the antigenic determinant that a part of the claimed polypeptide? What is the polypeptide sequence that comprises the antigenic determinant? How large is the polypeptide? What is the over all structure, sequence and function of the claimed polypeptide, especially in light of the evidence made of record showing sequence homology between Hemophilus, Helicobacter and Trichoderma longibrachiatum and that could share antigenic determinants ?

Claims 123, 132-133, 149, 212, and 220-224 are unclear because they depend from either claims 202 or 203.

Rejections Maintained/Newly Applied to Amended Claims

12. Claims 123, 132-133, 149, 202-203, 212 and 220-224 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial, a credible asserted utility or a well established utility as previously applied to claims 113-120, 123-125,127-135,149-150,196-213 and 214-224.

13. Claims 123, 132-133, 149, 202-203, 212 and 220-224 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a

way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record as previously applied to claims 113-120, 123-125,127-135,149-150,196-213 and 214-224.

14. Claims 123, 132-133, 149, 202-203, 212 and 220-224 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record on paper number 26, as previously applied to claims 113-120, 123, 132-133,149,196-201,204,205-212,214-219, 220-224.

Response to Arguments

15. Applicant's arguments filed October 30, 2000 have been fully considered but they are not persuasive, and will be addressed in so far as they would apply to claims 123, 132-133, 149, 202-203, 212 and 220-224 newly entered into the Application, submitted After Final March 4, 2002.

16. The rejection of claims 113-120, 123-125,127-135,149-150,196-213 and 214-224 under 35 U.S.C. 101, now applied to claims 123, 132-133, 149, 202-203, 212 and 220-224 is argued by Applicant:

> The present invention features a novel surface protein from the bacteria Helicobacter pylori. Applicant has described the chemical, physical and biological properties of the polypeptide set forth as SEQ ID

> NO 764. Applicant asserts that the polypeptides of the invention can be used for diagnostic and therapeutic purposes with regard to H.pylori infection; for generating antibodies; and to evaluate compounds useful as activators or inhibitors of the bacterial life cycle

it is further asserted:

> 'the polypeptide set forth as SEQ ID No 764 is a surface protein of the H.pylori pathogen, and, as such, is an attractive target for intervention.'

17. Upon consideration of Applicant's arguments that the invention is :

a."the amino acid sequence of SEQ ID NO 764 (page 5, paragraph 2, lines 1-2);

b.the polypeptide "is an attractive target for intervention"(page 5, paragraph 4, lines 2-3);

c.the utilities are defined as "proposed utilities of the claimed polypeptides" (page 5, paragraph 5, line 1);

d.arguments based upon publications after the filing date of the instant Application which characterize proteins that 'correspond substantially' to SEQ ID NO 764:(page 6, paragraph 1, lines 10-11), the examiner has taken the position that the claimed invention is not limited to SEQ ID No 764, but is drawn to polypeptides that share as few as 10 amino acids of SEQ ID NO 764, a sequence of 148 amino acids. The claimed invention may comprise 10, 16, 20, 50 or 100 amino acids selected from SEQ ID NO 764 consecutively. The resulting polypeptide need not look anything like SEQ ID NO 764, especially when it only shares as little as 6.7 % of the over all sequence of SEQ ID No 764 (10 of 148 amino acids).

A representative number of species for the claimed genus of polypeptides have not been described, nor have they been enabled as diagnostic or vaccine polypeptides. Just because a polypeptide is a defined as a surface polypeptide, does not automatically define the polypeptide as a diagnostic or vaccine antigen.

Even if the claimed invention were limited to just SEQ ID NO 764, the asserted biological activity of a polypeptide molecule is not defined by a linear sequence of amino acids. While a SEQ ID NO provides insight into the overall molecular structure, and the physical characteristics of the individual components, the SEQ ID NO does not define biological activity of the three dimensional polypeptide molecule in the native context. The biological activity of SEQ ID NO 764 has not been described in the instant Specification.

The cited references, Doig et al (1995) and Bains et al (2000), supplied by Applicant, compare SEQ ID NO 764 to the protein of Bains et al, which has been 'shown to be antigenic in vivo with both patient sera and specific monoclonal antibodies'. It is clear to the examiner that the antigen of Bains induces antibodies, these antibodies are present in patients that are still sick. The antibodies induced in vivo are not protective antibodies because infection persists. The protein of Bains has 250 amino acids and functions as a porin. The claimed polypeptide of SEQ ID No 740 only has 148 amino acids and no credible asserted specific utility in light of evidence of sequence homology with two other pathogens, Hemophilus and Trichoderma longibrachiatum. The protein of Bains is not defined as the same polypeptide as the instantly claimed invention, but is argued to 'correspond substantially'. The instant specification does not define SEQ ID No

764 as corresponding substantially to the porin of Bains. What the meaning of the phrase 'corresponds substantially' means with respect to SEQ ID No 764 has not been defined the instant specification.

The polypeptide of the invention is argued to be immunogenic and could induce antibodies which in turn could be used to identify the polypeptide, how circular reasoning defines a substantial, credible or well established utility has not been established.

18. Applicant urges, due to homology between P2 protein and the claimed polypeptides of SEQ ID NO 764, the polypeptides of SEQ ID NO 764 would have shared characteristics, and biological activity and thus would have diagnostic and vaccine utility.

19. It is the position of the examiner that the disease conditions caused by H.pylori and Hemophilus influenza are very different. The virulence factors associated with each of these pathogens also differ. The regions of the body that each pathogen infects and causes disease are not the same.

Comparison of SEQ ID NO 764 with Hemophilus influenza P2 porin, does not define SEQ ID No 764 as having the same biological characteristics as the claimed polypeptides. H.pylori vaccines are not predictable. Monath, Heap and Dunkley all show the induction of significant immune responses to H.pylori antigens without the induction of an immune response that protects against infection.

Comparison of SEQ ID NO 764 with Hemophilus influenza porin protein P2 (US Pat. 6,153,406) shows instant SEQ ID NO 764 (148 amino acids) shares **43 amino acids** with SEQ ID NO 10 (342 amino acids) of Tai et al (alignment previously provided) .

Comparison of SEQ ID NO 764 with H.pylori multimeric urease (US Pat.5,837,240) shows SEQ ID No 764 (148 amino acids) shares **40 amino acids** with the overall sequence of SEQ ID No 12 (518 amino acids) of Lee (alignment previously provided) .

Comparison of SEQ ID NO 764 with EG III cellulase (US Pat. 5,475,101) from Trichoderma longibrachiatum shows that SEQ ID NO 764 (148 amino acids) shares **35 amino acids** with SEQ ID NO 13(221 amino acids) of Ward et al (alignment previously provided) .

Comparisons made based upon sequence alignment of SEQ ID NO 764 with microbial proteins known in the art does not define the biological activity of SEQ ID NO 764 as that of the proteins that have shared homology. The sequence alignments show homology between three very different proteins of different lengths and different functionalities. The cellulase of Ward shows that greatest over all sequence similarity relative to the size of the full length polypeptide.

Polypeptides that comprises 10 amino acids or more of SEQ ID NO 764 would not have a specific utility based upon shared sequence homology/cross-reactivity with other known pathogens, Hemophilus and Trichoderma.

20. Argument is made that no evidence has been made of record that questions the asserted utilities for SEQ ID No 764:

> ' No evidence has been made of record that Applicant's assertions regarding utilities of the claimed polypeptides as diagnostic and/or therapeutic agents for H.pylori would not be considered credible to one of skill in the art.(page 6, paragraph 2, lines 5-7)'.

21. Upon consideration of the arguments and the references submitted by Applicant, the examiner believes that evidence has been made of record that defines portions of SEQ ID NO 764 to evidence antigenic cross reactivity with the P2 porin of Hemophilus pathogen . The existence of cross reactive epitopes would induce cross reactive antibodies which would result in a false positive diagnostic result. Therefore, Applicant has made of record arguments and evidence that polypeptides of SEQ ID No 764 would not serve as a diagnostic polypeptide for H.pylori infection due to the existence of conserved portions of SEQ ID NO 764 being shared with H.influenzae, both are human pathogens.

With respect to arguments made regarding evidence to show that SEQ ID No 764 is not a vaccine antigen, the examiner would like to point out the fact that Rappouli et al (1993) and HP World Wide (1991) documents have previously been made of record which show that H.pylori vaccines are in the developmental stages and are not predictable. HP World Wide cites Dunkley and Heap that found H.pylori compositions did not induce protective immunity. No showing has been made of record that indicates that the conserved portions of the H.influenza P2 porin are

those portions responsible for the induction of protective immune response against H.influenza, and that these conserved portions would also induce a protective immune response against Helicobacter pylori as well. Therefore, arguments that H.influenza P2 protein and Helicobacter polypeptide SEQ ID No 764 are both protective antigens are not convincing.

The rejection made of record under 35 U.S.C. 101, is maintained and the enablement rejection is maintained as well, for the same reasons made of record and responses above with respect to the lack of utility of the claimed polypeptides.

22. The rejection of claims 113-120, 123, 132-133, 149, 196-201 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is argued (see page 15, paper number 28, paragraph 3) through asserting that there is adequate description of the claimed invention:

> 'the claimed genus of polypeptides having at least 60% sequence identity with SEQ ID NO: 764 and polypeptides encoded by a nucleic acid sequence which hybridizes under high stringency conditions to the complement of a nucleotide sequence encoding SEQ ID NO 764 is identified by structural features that are described in the specification, recited in the claims, and commonly possessed by its members.'

23. In response to Applicant's assertion, it is the position of the examiner that while the instant specification suggests polypeptides of the recited structural components held in common with

SEQ ID NO 764, no structural polypeptides of the same functional characteristics of SEQ ID NO 764 have been described. The examiner has made a lack of written description for the claimed genus of polypeptides.

Applicant quotes the interim guidelines and focuses on the structure of the claimed polypeptide as the relevant identifying characteristic. The Interim Guidelines emphasizes the importance of disclosing relevant identifying characteristics.

As discussed above, the only physical characteristic disclosed is the amino acid sequence, the only structural characteristic disclosed is the amino acid sequence and the only chemical characteristic disclosed is that presented by the amino acid sequence. Only the SEQ ID NO is disclosed to describe the invention. A representative number of polypeptides that differ from SEQ ID No 764, and that would also evidence the same or equivalent biological function do not evidence original descriptive support.

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. Similarly, applicants have not disclosed any information which is 3' and 5' to the polynucleotide sequence of SEQ ID NO:764 and therefore clearly lacks written description for the broad class of

polynucleotides encoding SEQ ID NO:764. In the instant case, the specification provides only written description for a polypeptide that is encoded by a polynucleotide consisting of SEQ ID NO:764. No variant polypeptides have been described in such a way to reasonably convey to one skilled in the relevant art that Applicant had possession of the claimed invention.

For arguments sake, assume that the gene that encodes the full length Helicobacter pylori protein that comprises the now claimed polypeptide is within the scope of the claimed invention based upon the claim language recited. The claimed invention, SEQ ID NO 764, has not been described as the full length coding region of a protein, but an isolated polypeptide that comprises SEQ ID NO 764 would read on a full length protein, which would be encoded by the gene for the protein. As the term polypeptide encompasses proteins, the scope of the claimed invention encompasses the full length protein that comprises SEQ ID NO 764. Helicobacter polypeptides (proteins) that are larger than 148 amino acids and comprise SEQ ID NO 764 lack original descriptive support in the instant specification. The amino acid sequence shown in HPP426 starts with a "Met" but the end of the sequence is not defines through the nucleic acid sequence that encodes the amino acid/polypeptide to have (TATA box) stop showing that the sequence is representative of a full open reading frame for a complete protein.

24. What the sequence of the isolated polypeptide with the recited characteristics defined in claims 202-203, other than the disclosed SEQ ID No 764, does not evidence original descriptive support. A single disclosed species does not provide original descriptive support and show

possession for the now claimed genus of polypeptides as now claimed in claims 123, 132-133, 149, 202-203, 212 and 220-224.

With respect to the claimed polypeptides of claims, it is the position of the examiner that the claim is described for Helicobacter polypeptides up to 148 amino acids that are encoded by SEQ ID No 764. Helicobacter polypeptides larger that 148 amino acids and comprise SEQ ID NO 764 do not evidence original descriptive support. As no upper limit is recited in the claim, Helicobacter pylori polypeptides greater than 170 amino acids are encompassed by the claim language which do not meet the requirement for written description.

For example, Applicant submitted Bains et al (published in year 2000) as 'substantially corresponding' to the claimed invention. The protein (a type of polypeptide), of Bains, comprises 250 amino acids and comprises at least 10, 16, 20, 50 and 100 amino acids of a naturally occurring Helicobacter polypeptide. The protein of Bains is not described in the instant specification, the document was published in year 2000, therefore, even though there is substantial correspondence of the claimed invention to the polypeptide of Bains, original descriptive support for polypeptides that comprise SEQ ID No 764 and are larger than the 148 amino acids of Seq ID NO 764 do not meet the written description requirement under 35 U.S.C. 112, first paragraph.

Conclusion

25. This is a non-final action.

26. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

27. Tufano et al (April 1994) is cited to show H.pylori porins activity lymphocytes.

28. Exner et al (April 1995) is cited to show H.pylori porins.

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

April 30, 2002

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600